NATIONAL DEAFNESS AND OTHER COMMUNICATION DISORDERS ADVISORY COUNCIL

January 31, 2003

National Institutes of Health
Bethesda, Maryland

MINUTES

The National Deafness and Other Communication Disorders Advisory Council convened on January 31, 2003, in Conference Room 6, National Institutes of Health (NIH), Bethesda, MD. Dr. James F. Battey, Jr., Director, National Institute on Deafness and Other Communication Disorders (NIDCD), served as Chairperson. In accordance with Public Law 92-463, the meeting was:

Open: January 31, 2003: 8:30 a.m. to 11:30 a.m., for the review and discussion of program development, needs and policy; and

Closed: January 31, 2003: 12:30 p.m. to 2:15 p.m. for review of individual grant applications.

Council members in attendance:[1]

Dr. Noma Anderson
Dr. Gary K. Beauchamp
Dr. Gail D. Burd
Dr. Patricia D. Cayne
Dr. Richard A. Chole
Dr. Judy R. Dubno
Dr. Beverly S. Emanuel
Ms. Susan M. Greco
Dr. Ronald R. Hoy
Dr. Ray D. Kent
Dr. David J. Lim
Dr. Nicolas Linares-Orama
Dr. Miriam H. Meisler
Dr. Richard T. Miyamoto
Dr. Adrian A. Perachio
Ms. Donna L. Sorkin
Dr. Ingo R. Titze
Ms. Heather Whitestone- McCallum

Council members not participating:

Dr. John P. Madison

1 For the record, it is noted that members absent themselves from the meeting when the Council is discussing applications (a) from their respective institutions or (b) in which a real or apparent conflict of interest might occur. This procedure applies only to individual discussion of an application and not to "en bloc" actions.

Ex-Officio Members present:

Dr. Lucille B. Beck

Ex-Officio Members absent:

Dr. John R. Franks
Dr. Michael E. Hoffer

The Council roster is found as Appendix 1.

Various members of the public, as well as NIDCD staff and other NIH staff, were in attendance during the open session of the Council meeting. A complete list of those present for all or part of the meeting is found in Appendix 2.

I. Call To Order and Opening Remarks .....Dr. James F. Battey, Jr.

The meeting was called to order by Dr. Battey, Director, NIDCD, who thanked Council members for their service and advice to the Institute. Dr. John Madison and Dr. Michael Hoffer had conflicts which prevented them from attending today's meeting.

II. Council Procedures .....Dr. Craig A. Jordan

Procedural Matters

Dr. Jordan discussed important procedural matters, including requirements imposed by the Government in the Sunshine Act and the Federal Advisory Committee Act. The necessity of members avoiding conflict of interest, or the appearance thereof, was stressed, as was the need to maintain confidentiality concerning the proceedings and materials related to the closed portion of the meeting. Dr. Jordan announced that the Council meeting would be open to the public during the morning session, but would be closed for consideration of grant applications during the afternoon.

Consideration of Minutes of the Meeting of September 13, 2002

Dr. Battey called members' attention to the minutes of the September 13, 2002 meeting of the Advisory Council. The minutes were approved as written.

Confirmation of Dates for Future Council Meetings

Dates for the Council meetings through September 2004 have been established. A list of these meetings was distributed to the Council members. The next meeting of Council is scheduled for Friday, May 16, 2003 on the NIH campus, Bethesda, Maryland.

III. Report of the Director, NIDCD .....Dr. Battey

NIH Stem Cell Task Force

Dr. Battey updated the Council on activities of the NIH Stem Cell Task Force, for which he serves as Chair. The purpose of the NIH Stem Cell Task Force is to enable and accelerate the pace of stem cell research by identifying rate limiting resources (both material and human) and develop initiatives to enhance these resources; and to seek the advice of scientific leaders in stem cell research about the challenges to moving the stem cell research agenda forward and strategies NIH may pursue to overcome these challenges.

Dr. Battey discussed the proposed actions of the Task Force, which include continuing the infrastructure award program; characterizing cell lines; stimulating more research on basic biology; and training investigators to culture and use stem cells. He also discussed some of the scientific challenges involved with stem cell research. Among these challenges are building scientific capacity, proving long-term stability of cells, understanding cell cycle control, understanding cell specialization, and evaluating cell-host interactions. Dr. Battey talked about the coordination of NIH Stem Cell Research Program Strategies between the task force working groups and NIH.

As of December 13, 2002, NIH had made seven infrastructure awards, nine investigator-initiated awards, forty administrative supplements, two pilot and feasibility projects, and one postdoctoral fellowship, totaling approximately $20.5 million.

Copies of the slides Dr. Battey used for his stem cell presentation are included in these minutes as Appendix 3.

Budget Considerations:

In his discussion of the Institute's budget, Dr. Battey described how the $262.8 million available for new and competing research project grants in the amended President's Budget has been allocated for FY2003. From this total, $8.2 million is reserved for Small Business innovation (SBIR) and technology transfer grants (STTR), $1.6 million for administrative supplements, $183.8 million for commitments to noncompeting grants, $1.4 million for carryover commitments from FY2002, and $11 million for program requirements in FY2003. Twenty percent of the remaining $56.7 million is designated for High Program Priority (HPP). When apportioned for the three Council meetings in FY 2003, $3.78 million is available for HPP applications at the January meeting. The budget has $15.1 million available for the May Council's initial payline, which allows funding of all R01 applications to the 26th percentile, plus additional HPP applications. Copies of the slides Dr. Battey used for his budget presentation are included in these minutes as Appendix 4.

Future Year NIDCD Budget Discussions

Council members commented about the likelihood of NIDCD receiving significantly smaller budget increases in future years following Congress's efforts to double the NIH budget and questioned Dr. Battey about potential strategies to respond to such a situation. Dr. Battey indicated that

NIDCD staff had initiated such discussions and that a number of possible cost saving strategies could be considered. Currently, the uncertainties about the FY2003 budget and the unknown nature of the President's proposed FY2004 budget have precluded any significant modeling efforts. Council members discussed several cost cutting options that could be used to conserve monies and preserve a reasonable payline during times of lean budgets. Such options included decreasing funds for trans-NIH activities, decreasing funds for Requests for Applications and other set-aside initiatives, or slightly reducing funds for non-competing awards. Council members had conflicting opinions/perspectives on these options. Members did recommended that NIDCD staff factor in the impact any cost saving measures might have on the support and retention of new investigators, since support of new investigators is a high priority regardless of the economic situation. Dr. Battey proposed that the discussion of possible cost saving scenarios might be better pursued at a future meeting when firmer budget data would allow the size of any potential problem and the impact of selected scenarios to be estimated.

IV. Report of the Division of Extramural Research ..... Dr. Jordan and Dr. Cooper

Dr. Robert Dobie, former Director, Division of Extramural Research, left the NIDCD in December to accept a position with the Department of Otolaryngology, University of California at Davis. Dr. Battey informed the Council of his plans to return to a prior organizational structure with scientific review and grants management in one division, and program in a separate division. He announced that Dr. Jordan will be the acting division director for review and grants management, and Dr. Judith Cooper will be the acting division director for program. Dr. Battey added that his decision is a reflection of his unqualified confidence in the leadership qualities of Drs. Cooper and Jordan.

Dr. Jordan and Dr. Cooper presented the report of the Division of Extramural Research.

Implementation Plan

Dr. Cooper announced that the FY 2002-03 Implementation Plan was recently posted on the Council's website.

Meeting with Research Core Centers (P30) Principal Investigators

Dr. Cooper mentioned the plans for a two-day meeting with Research Core Center (P30) principal investigators on March 26-27, 2003. The purpose of this meeting, coordinated by Dr. Amy Donahue, is to exchange information and ideas related to the P30 mechanism. Plans include discussion of common scientific/administrative issues, including ongoing core activities. Part of the meeting will be spent looking to the future, including discussion of how P30 activities and resources might be shared with the larger research community.

[*Executive Secretary's note: Because of the war in Iraq, and the resulting concern expressed by participants regarding travel to Bethesda, this meeting was not held in March; it has been re-scheduled for July 21-22.]*

Support from Office of Rare Diseases

The NIH Office of Rare Diseases (ORD) has provided funds to the NIDCD to support a Workshop on Neurological Disorders and Associated Speech and Swallowing Problems. This workshop, which is being coordinated by Dr. Lana Shekim, will be held in the spring.

The ORD will also help support a conference on cochlear implants through a Research Conference Grant (R13). This conference will be held April 24-26, 2003. Dr. Donahue is the Institute's contact person for the conference.

NIDCD Restrictions on the P50 Mechanism

Dr. Cooper reported that the NIDCD has placed new budgetary restrictions on the P50 mechanism. An announcement has been published in the NIH Guide to Grants and Contracts to alert the research community. Details about these restrictions can be found at: http://www.nidcd.nih.gov/funding/types/p50.asp.

Endorsement of Council Operating Procedures

Dr. Jordan called Council's attention to a copy of the Council Operating Procedures which had been provided to each member prior to the meeting. The Council Operating Procedures state those actions which Council empowers staff to take without formal Council approval. It is the NIDCD's procedure to review the Council Operating Procedures annually at the January meeting of Council. There are no recommended changes to the document this year, so this version is identical to the version approved last January. The document was endorsed unanimously for the current year, and is included in these minutes as Appendix 5.

Scientific Review Branch Staff

In an effort to keep Council informed about the responsibilities handled by various components of the NIDCD, Dr. Jordan introduced the staff of the Scientific Review Branch (SRB). The SRB directs and carries out the scientific and technical merit review of a wide array of grant applications and contract proposals that cover the spectrum of science supported by NIDCD (including clinical research centers, core centers, research training, career development, and special initiatives). It was noted that for this particular Council meeting the SRB reviewed approximately 50% of the grant applications assigned to the NIDCD. Dr. Jordan introduced the Scientific Review Administrators of the SRB: Dr. Melissa Stick, who manages the Communication Disorders Review Committee; Dr. Stan Oaks, who manages the review of the NIDCD Small Grant Program; Dr. Ali Azadegan, who manages Special Emphasis Panels for specialized review needs; and, Dr. Sheo Singh, who recently joined the Branch and will manage Special Emphasis Panels.

V. Biennial Council Review of NIDCD .....Dr. A. Julianna Gulya
Compliance with Inclusion Guidelines

On a biennial basis, the advisory councils of the institutes comprising the National Institutes of Health (NIH) are asked by the Office of Research on Women's Health to review the procedures used by their respective institutes to implement the 1994 NIH guidelines for the inclusion of women and minorities in clinical research. The previous review was performed in 2001. It is again time for Council to review NIDCD implementation of the 1994 NIH Guidelines, and to certify NIDCD's compliance with them.

The report entitled "NIDCD 2003 Biennial Advisory Council Report Certifying Compliance with Inclusion Guidelines," and six appendices to this report, containing background material, summary data tables, etc., were e-mailed to Council members and posted on the Council website to allow time for their review prior to the meeting.

Dr. Gulya led the discussion and responded to questions about the report and these guidelines, after which a vote was taken. The Council voted unanimously to certify that the NIDCD process is in compliance.

VI. The Growth of the NIDCD R03 Small Grant Program .....Dr. Barry Davis

In an effort to keep Council abreast of activities in the various programs of the Institute, the Institute periodically schedules a discussion of a particular program at its Council meetings. The R03 Small Grant Program, which has been active for more than twelve years, is a very popular program with NIDCD's beginning investigators, and has shown tremendous growth in the last three years. Dr. Barry Davis serves as the Program Coordinator for the Small Grants Program, and he presented information about the current status of the program and some analyses of application numbers, funded grants, and subsequent transition to R01 grants. He ended his presentation with the following five conclusions:

- R03 funding comes at a critical career point at the end of the postdoctoral experience or beginning faculty appointment, and helps establish a research direction. It often provides essential pilot data for an R01 application.

- The R03 serves as an important bridge to the R01 support for some, but not all beginning investigators require small grant support.

- 40-50% of all R03 recipients subsequently obtain R01/R29 support.

- Most R03 awardees who are successful in obtaining an R01 grant experience a lapse in support between the two grant awards.

- The NIDCD plans to continue monitoring the career paths of its new investigators.

Dr. Davis responded to questions from Council members and provided additional information when available.

VII. Council Member Presentation ..... Dr. Ron Hoy

Customarily, time is allotted on the agenda for various Council members to present a synopsis of their research, interests, and/or other efforts related to the broad interests of the communities served by NIDCD. This helps to familiarize staff and other members of Council with each member's research/expertise, and promotes stronger interactions among Council members and staff members. It also provides a wonderful opportunity for the cadre of accomplished individuals on Council to share their unique knowledge, abilities, and perspectives with the others.

Dr. Ron Hoy discussed his research into the sense of hearing possessed by insects.

Following is an abstract of his presentation:

The sense of hearing is possessed by only two major groups of animals: vertebrates, including humans of course, and insects. There is a remarkable variety of insect "ears," some of which solve the canonical problems of hearing, sound identification and sound localization, in truly innovative ways. The fly, *Ormia ochracea*, parasitizes crickets by hearing and homing in on the cricket's loud, chirping, mating call. In the course of evolution, the fly has "invented" a novel auditory mechanism for directional sensitivity and sound localization (mechanical coupling of its pair of eardrums), unlike any other in the animal kingdom.

The high sensitivity, acute directional sensitivity, and miniature size of the fly's ears (less than 0.5 mm diameter) have been exploited by a team of engineers as a novel design for a miniature hearing aid transducer that would mimic the performance of the fly's biological ears, especially their directionality, which would be an advance for hearing aid microphone design. The fly-ear inspired transducer consists of 3 innovations. First, the silicon microphone diaphragm is based on the fly's eardrums, is small (1 mm), sensitive, robust, and directional. Second, The sound-induced movements of the diaphragm is detected by an optoelectronically miniaturized laser which confers a 10 dB increase in the sensitivity over conventional miniature microphones that use capacitance coupling (piezo devices). Third, signal enhancing beam-forming algorithms will further increase the directional sensitivity of the microphones because these algorithms can be implemented by modern digital signal processing hardware that can be miniaturized and made part of the new hearing aid transducer package.

This novel design for a directional hearing aid transducer has great potential for improving the performance of hearing aids because the fabrication can be done cheaply using silicon based MEMS technology. What makes this integrated approach possible is that the front end of the device, the sound detecting diaphragm, is designed on the mechanical properties of the Ormia fly's ears, which in the realm of biology, "invented" a novel directional detector, unlike any other in nature. The project is a testament to the potential of the engineering strategy known as "biomimickry."

VIII. Council Member Presentation ..... Dr. Noma Anderson

Dr. Noma Anderson described her career in higher education. Currently Dr. Anderson is Director of the School of Health at Florida International University and she has been on the faculty at Hampton University and at Howard University. Her career has involved teaching, mentoring, and program administration at these three majority-minority institutions. Her educational focus has been preparing culturally and linguistically diverse students to become health professionals able to serve patients and families from culturally and linguistically diverse backgrounds. She has co-authored four texts. Dr. Anderson has been an American Council on Education (ACE) Fellow and American Speech-Language-Hearing Association (ASHA) Vice President for Academic Affairs. She has served the NIDCD previously by being on the Advisory Board from 1992-1994 and the Integrated Policy and Planning Board in 1995.

IX. Scientific Presentation..... Dr. Peter Mombaerts

Dr. Battey welcomed and introduced Dr. Peter Mombaerts, Associate Professor, and Head, Laboratory of Developmental Biology and Neurogenetics, The Rockefeller University New York, New York. Dr. Mombaerts discussed his research in a presentation entitled, “Olfaction Targeted."

Following is an abstract of his presentation:

The olfactory system provides sensory information about the chemical composition of the external world. Olfactory chemoreception initiates in mammals at the level of sensory neurons that are located in the main olfactory epithelium and the epithelium of the vomeronasal organ (VNO). The former mediates mainly the detection of volatile odorants. The VNO mediates mainly, but not exclusively, the detection of pheromones, chemical signals that provide information about gender, dominance and reproductive status between individuals of the same species.

The dichotomy between the main and vomeronasal (or accessory) olfactory systems is further reflected at the level of the molecules that serve as receptors, or putative receptors, for their respective sensory stimuli. In the main olfactory system, odorant receptor (OR) genes encode seven-transmembrane proteins and are members of a multigene family that ~1000 genes in mouse and human. In the accessory olfactory system, two vomeronasal (VR) superfamilies of genes encoding seven-transmembrane proteins have been proposed to encode pheromone receptors. There are no conserved motifs between the two VR superfamilies, and VRs have no sequence homology with ORs. We have provided the first functional evidence for VRs as pheromone receptors by removing a cluster of VR genes from the mouse genome through chromosome engineering technology.

Mining genomic databases, we composed a first near-complete draft of the mouse V1R repertoire, cataloguing 137 intact genes in 12 distinct families. Our exploration of the human V1R repertoire resulted in the discovery of the five human V1R genes with an intact open reading frame.

Axons of all neurons expressing a given OR converge onto defined glomeruli. Our genetic approach was designed to image axons of individual neurons expressing a particular OR. The method was based on gene targeting in embryonic stem cells and the histochemical marker taulacZ. We modified the OR gene P2 in the germ line of mice such that P2-expressing neurons can be stained blue along their entire length by virtue of their expression of taulacZ. In these mice, labeled axons converge to a pair of glomeruli in the main olfactory bulb, which reside at recognizable locations. This poses a formidable wiring problem in the main olfactory system. Additional genetic experiments have fueled the notion that the ORs are involved in the wiring of the main olfactory system, but they cannot be the only determinant. The OR thus fulfills two distinct roles: as a receptor for odorants, and as an axon guidance molecule. Glomeruli in the olfactory bulb show local permutations: their position is not as rigidly determined as previously thought. Three-dimensional reconstructions using two-photon microscopy revealed that the structure of glomeruli and axonal plexuses for a specific OR are idiosyncratic: no two glomeruli are alike.

Applying a similar genetic tagging approach, we demonstrated that axons of neurons expressing a particular VR gene converge onto numerous glomeruli in the accessory olfactory bulb. The pattern of axonal projections is complex and variable. However, the divergent pattern of axonal projections is reorganized in a convergent manner by the second-order neurons.

The issue of OR or VR gene choice remains unresolved: how does a neuron choose one gene for expression from a large repertoire of genes, spread throughout the genome? We have developed convenient model systems for OR gene regulation, and show that it is under short-range control: transgenes of a few kilobases are sufficient to mimic the many intricate features of OR gene expression.

CLOSED SESSION

X. Council Consideration of Pending Applications

The Council gave special attention to applications from foreign institutions and to applications involving issues related to protection of human subjects, animal welfare, biohazards and/or women/minority/children representation in study populations as identified by the initial review groups.

A. Traditional Research Project Grant (R01) Awards

1. Consideration of Applications: On the Council's agenda was a total of 107 research grant applications; 83 applications had primary assignment to NIDCD, in the amount of $22.6 million first-year direct costs. It is anticipated that, of the applications competing at this Council, NIDCD will be able to award grants to applications scoring through the 26.0 percentile.

B. Special Programs Actions

1. Small Grants (R03): The Council recommended support for sixteen applications.

2. Academic Research Enhancement Award (AREA) Grants (R15): The Council recommended support for two applications.

3. Small Business Technology Transfer (STTR). The Council recommended support for one Phase I (R41) application.

4. Small Business Innovation Research Awards (SBIR). The Council recommended support for four Phase I (R43) applications and three Phase II (R44) applications.

5. Center Core Grants (P30). The Council recommended support for one application.

6. Cellular Repair Studies of the Auditory and Vestibular Systems (DC-02-003). The Council recommended support for four R01s and one R21 application.

7. Augmentative and Alternative Communication Strategies (HD-02-002): The NICHD will fully fund two applications.

8. Autism Research Centers: The STAART Program (MH-03-005): The Council recommended support to co-fund two applications.

9. Exploratory/Developmental Research Feasibility Pilot Studies (PAR-02-088): The Council recommended support for ten applications.

C. Training Programs

1. Institutional National Research Service Awards (T32): The Council recommended support for eight applications.

XI. Adjournment: The meeting was adjourned at 2:15 p.m. on January 31, 2003.

XII. Certification of Minutes

We certify that, to the best of our knowledge, the foregoing minutes and attachments are accurate and correct.[2]

_____ _____

Craig A. Jordan, Ph.D.
Executive Secretary
National Deafness and Other Communication
Disorders Advisory Council

_____ _____

James F. Battey, Jr., M.D., Ph.D.
Chairman
National Deafness and Other Communication
Disorders Advisory Council

Director
National Institute on Deafness and
Other Communication Disorders

Jeannie Combs
Council Assistant

2 These minutes will be formally considered by the Council at its next meeting; corrections or notations will be incorporated in the minutes of that meeting.

APPENDICES

PAGE

Roster

National Deafness and Other Communication Disorders Advisory Council

Chairperson
James F. Battey, Jr., M.D., Ph.D., Director
National Institute on Deafness and Other Communication Disorders
Bethesda, Maryland 2089

ANDERSON, Noma B., Ph.D. 2006
Director and Professor
Florida International University
School of Health
Miami, FL 33199

BEAUCHAMP, Gary K., Ph.D. 2005
Director and President
Monell Chemical Senses Center
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BURD, Gail D., Ph.D. 2003
Professor and Interim Head
Dept of Molecular and Cellular Biology
University of Arizona
Tucson, Arizona 85721

CAYNE, Patricia D., Ph.D. 2006
Educational Neuropsychologist
Private Practice
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CHOLE, Richard A., M.D., Ph.D. 2005
Lindburg Professor and Head
Department of Otolaryngology
Washington University School
of Medicine
St. Louis, Missouri 63110

DUBNO, Judy R., Ph.D. 2003
Professor
Department of Otolaryngology-
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Medical University of South Carolina
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EMANUEL, Beverly S., Ph.D. 2004
Abramson Research Center, Rm. 1002
Children's Hospital of Philadelphia
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GRECO, Susan M. 2006
Executive Director
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HOY, Ronald R., Ph.D. 2003
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KENT, Ray D. Kent, Ph.D. 2006
Professor
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University of Wisconsin
Madison, WI 53705-2280

LIM, David J., M.D. 2005
Executive Vice President, Research
Head, Dept of Cell and Molecular Biology
House Ear Institute
Los Angeles, California 90057

LINARES-ORAMA, Nicolas, Ph.D. 2004
Professor of Language Pathology
Director, Filius Institute
University of Puerto Rico
San Juan, PR 00936-4984

MADISON, John P., Ed.D. 2004
Associate Professor (Retired)
Department of English
National Technical Institute for the Deaf
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MEISLER, Miriam H., Ph.D. 2003
Professor Human Genetics Department
School of Medicine
University of Michigan
Ann Arbor, Michigan 48109-0168

MIYAMOTO, Richard T. M.D. 2006
Professor & Chairman
Department of Otolaryngology
Indiana University
School of Medicine
Indianapolis, IN 46202

PERACHIO, Adrian A., Ph.D. 2006
Professor & Vice President for Research
Department of Otolaryngology
University of Texas Medical Branch
Galveston, TX 77555-0130

TITZE, Ingo R., Ph.D. 2004
Distinguished Professor
Department of Speech Pathology
and Audiology
University of Iowa
Iowa City, IA 52242

WHITESTONE-MCCALLUM, Heather 2005
President
Heather-Leigh Whitestone, Inc.
Atlanta, GA 30339

EX-OFFICIO MEMBERS:

BECK, Lucille B., Ph.D.
Director
Audiology & Speech Pathology Service
Department of Veterans Affairs
Washington, D.C. 20422

FRANKS, John R., Ph.D.
Chief, Bioacoustics and Occupational
Vibration Section
Physical Agent Effects Branch
Division of Biomedical and Behavioral Science
National Inst for Occupational Safety & Health
Cincinnati, Ohio 45226

HOFFER, Michael E., M.D.
Co-Director
Department of Defense Spatial Orientation Center
Department of Otolaryngology
Naval Medical Center
San Diego, California 92134-5000

THOMPSON, The Honorable Tommy G.
Secretary
Department of Health and
Human Services
Washington, D.C. 20201

ZERHOUNI, Elias Adam, M.D.
Director
National Institutes of Health
Bethesda, Maryland 20892

EXECUTIVE SECRETARY

JORDAN, Craig A., Ph.D.
Chief, Scientific Review Branch
Division of Extramural Research, NIDCD
Bethesda, Maryland 20892-7180

Rev. January 2003

Appendix 2

ATTENDANCE LIST

Other than Council members, attendees at the January 31, 2003 Council meeting included:

NIDCD Staff:

Office of the Director
Luecke, Donald H., M.D., Deputy Director

Office of Health Communication and Public Liaison
Allen, Marin, Chief
Wenger, Jenny

Office of Administration
Kerr, W. David, Executive Officer

Financial Management Branch
Rotariu, Mark, Budget Officer
Lee, Mimi, Budget Analyst

Information Systems Management Branch
Jones, Jackie, Chief

Science Policy and Planning Branch
Wong, Baldwin, Chief
Cole, Laura, Ph.D., Science Policy Analyst
White-Olsen, Anne, Program Analyst

Division of Extramural Research
Combs, Jeannie, Program Analyst
Holmes, Debbie, Secretary
Stephenson, Nanette, Program Assistant

Grants Management Branch
Stone, Sara, Chief
Dabney, Sherry, Grants Management Officer
DaSilva, Maria, Program Assistant
Doan, Hoai, Grants Management Specialist
Hamilton, Gail, Grants Management Specialist
McNamara, Castilla, Grants Management Specialist
Ranney, Meigs, Grants Management Officer

Scientific Programs Branch
Cooper, Judith, Ph.D., Chief; and Program Director, Language

Voice, Speech, Language, Smell and Taste Section
Davis, Barry, Ph.D., Program Director, Taste and Smell Program
Shekim, Lana, Ph.D., Program Director, Voice, Speech and Language

Hearing and Balance/Vestibular Section
Donahue, Amy, Chief; and Program Director, Hearing
Freeman, Nancy, Ph.D., Program Director, Hearing
Luethke, Lynn, Ph.D., Program Director, Hearing
Miller, Roger, Ph.D., Program Director, Hearing

Clinical Trials, Epidemiology and Biostatistics Section
Gulya, Julie, M.D., Chief, Program Director, Clinical Trials
Hoffman, Howard, Program Director for Epidemiology & Biostatistics
Jelen, Janet, Computer Specialist
Chiu, May, Program Analyst

Scientific Review Branch
Jordan, Craig A., Ph.D., Chief
Azadegan, Ali, D.V.M., Ph.D., Scientific Review Administrator
Oaks, Stanley C., Ph.D., Scientific Review Administrator
Singh, Sheo, Ph.D., Scientific Review Administrator
Stick, Melissa J., Ph.D., M.P.H., Scientific Review Administrator

Division of Intramural Research
Wenthold, Robert, Ph.D., Director

Center for Scientific Review, NIH
Kimm, Joseph, Ph.D., Health Scientist Administrator
Miller Sostek, Anita, Division Director, Clinical and Population-Based Studies
Weijia Ni, Scientific Review Administrator

Others
Ford, Folami, Interpreter
Mombaerts, Peter, M.D., Ph.D., Associate Professor, Rockefeller University
Wetzel, Alissa, Interpreter

Appendix 3

NIH Stem Cell Research Program Report

As Presented By

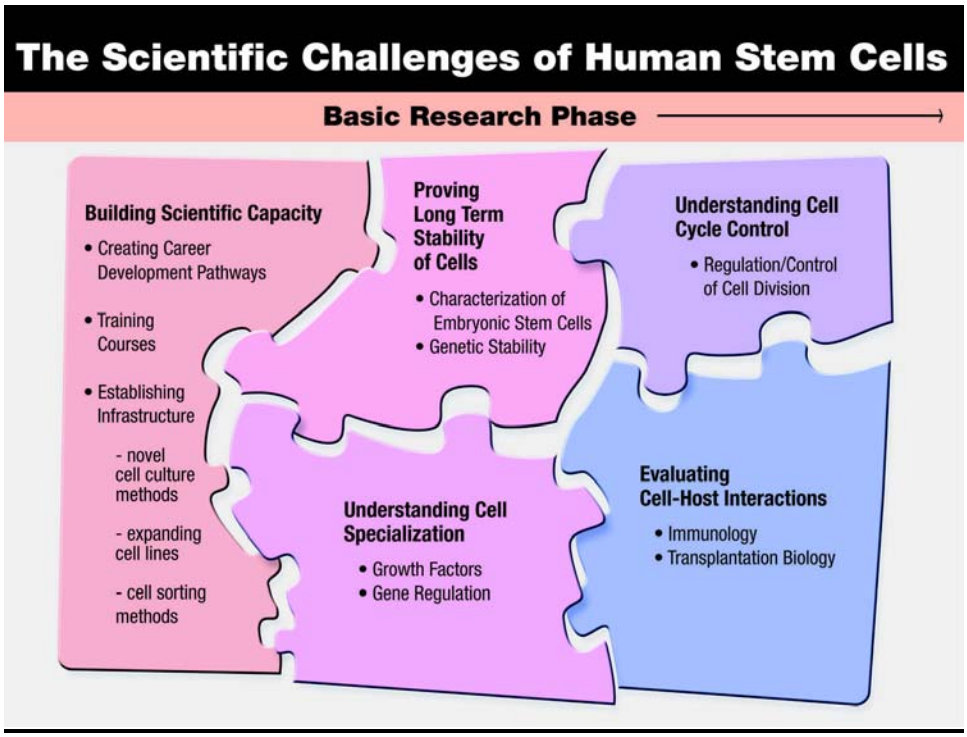
James F. Battey, Jr., M.D., Ph.D.
Director, NIDCD

NDCD Advisory Council Meeting

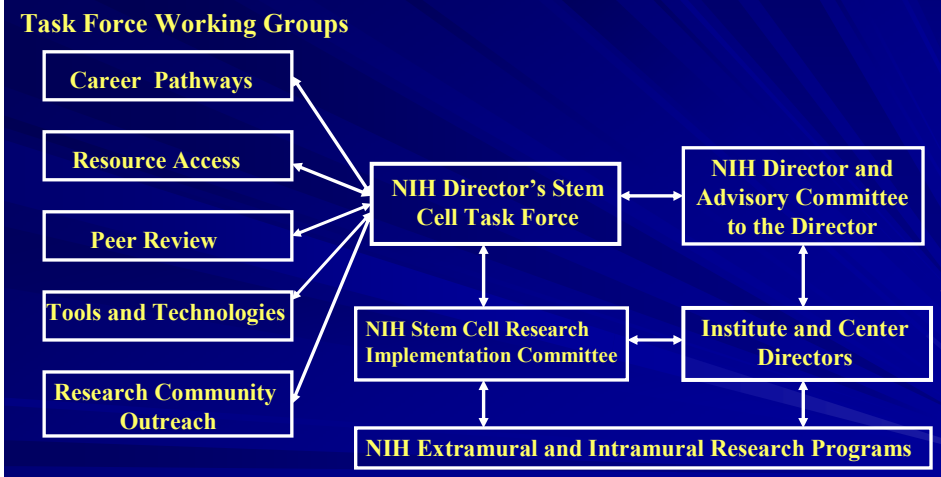
January 31, 2003

Discovery: Stem Cell Biology Proposed Actions

- Continue infrastructure award program
- Characterize cell lines
- Stimulate more research on basic biology
- Train investigators to culture and use stem cells



Coordination of NIH Stem Cell Research Program Strategies



stemcelltaskforce.nih.gov

NIH hESC Awards

7 Infrastructure Awards	$ 5,547,159
9 Investigator-initiated Awards	$11,394,400
40 Administrative Supplements	$ 3,931,790
2 Pilot & Feasibility Projects	$ 476,447
1 Postdoctoral Fellowship	$ 48,148

December 13, 2002

Infrastructure Awards (R24)

- Awards to organizations with entries on NIH hESC Registry available for Federal funds to develop into distribution-quality cell lines
- Two year period of support
- Seven awards for total of $5,547,159
- Led to development of nine hESC lines ready for shipment with more to come in near future
- PA recently re-issued with receipt dates in February and May 2003

Program Announcements (PAs)

- Short-term Courses in Human Embryonic Stem Cell Culture Techniques
  - T15 Mechanism (Continuing Education Training)
  - Supported by 11 NIH Institutes
  - Issued February 2002
  - $1M direct costs committed (FY2002)
  - Three-year support ($150,000/year direct maximum)
  - Receipt dates (April 23, 2002 and October 23, 2002)
  - Reissued for receipt date (Jan-Mar 2003)

Program Announcements

- Career Enhancement Award for Stem Cell Research (K18) and Career Development Award (K08, K23)
- Release: March 1, 2002; Expire: June 1, 2005
- NIDDK, NIAAA, NINR, NIAID, NHLBI
- Mid-career investigators, 6-24 month salary and $50,000 direct/year
- Training to use stem cells in research
  - grants.nih.gov/grants/guide/pa-files/PAR-02-069.html

Requests for Applications (RFAs)

- Exploratory Center Grants for hESC Research (NIGMS) (Letter of intent 2/13/03; receipt date 3/13/03)
- Multi-investigator teams to conduct research using hESCs
- Infrastructure, growth and maintenance, biochemical/ molecular markers for hESCs, unique properties of hESCs, pilot studies
- P20 Exploratory Center Grant, leading to P50 application
- $2M in 2003, funding 2-3 P20 grant applications for up to 3 years at $500,000 direct/year

Additional PAs/RFAs

- Innovative Concepts and Approaches to Developing Functional Tissues and Organs for Heart, Vascular, Lung, and Blood Applications (R21) (NHLBI)
- Plasticity of Human Stem Cells in the Nervous System (R01) (NINDS, NIA, NIMH, NHLBI)
- Basic and Applied Stem Cell Research for Arthritis and Musculoskeletal Diseases (RO1) (NIAMS)
- Stem Cells in Development/Repair of Orofacial Structures (NIDCR)

Additional PAs/RFAs

- Basic Research on Mesenchymal Cell Biology (NIA, NHLBI)
- Comprehensive Programs in Beta Cell Biology (NIDDK)
- Cellular Repair Studies of the Auditory and Vestibular System (NIDCD)
- Research on Stem Cell Biology and Cell-based Therapies for Heart, Lung, Blood, and Sleep Disorders (NHLBI)
- Stem Cell Research for Alcohol-related Disorders (NIAAA)

NIH Intramural Research

- Six laboratories at NIH are currently using hESC in their research
- Expanding interest as cell line availability becomes more straightforward
- Considering development of stem cell characterization unit within Intramural Research Program

NIH Stem Cell Web Sites

- Stem Cell Information
  - www.nih.gov/news/stemcell
- Human Embryonic Stem Cell Registry
  - escr.nih.gov
- Stem Cell Task Force
  - stemcelltaskforce.nih.gov
- E-mail Contact for Stem Cell Registry
  - stemcell@mail.nih.gov

Appendix 4

NIDCD Director's Budget Report

As Presented By

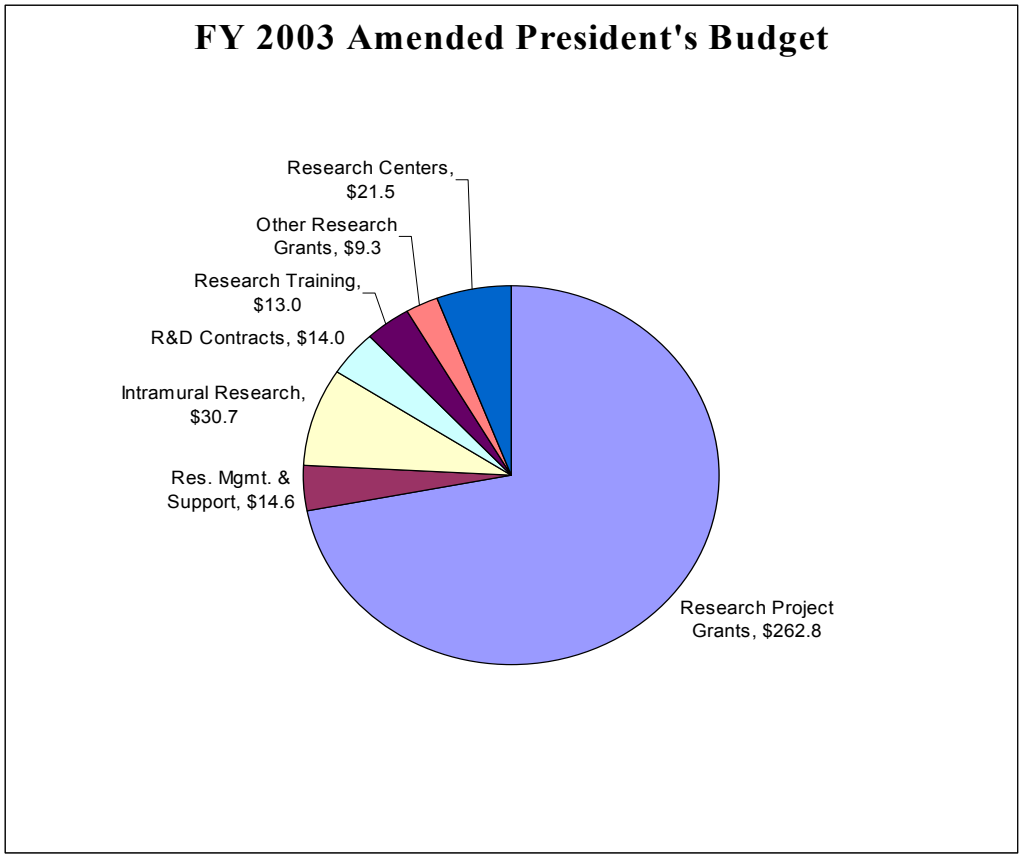
James F. Battey, Jr., M.D., Ph.D.
Director, NIDCD

NDCD Advisory Council Meeting

January 31, 2003

National Institute on Deafness and Other Communication Disorders
Budget Mechanism

(Dollars in millions)



National Institute on Deafness and Other Communication Disorders

January 2003 Council
Competing Research Project Grants
(Dollars in thousands)

Total RPG Funds FY03 Amended President's Budget		$ 262,754
Less SBIR/STTR Budget		-8,243
Less Admin. Suppl. Budget		-1,600
Less Estimated RPG Noncompeting		-183,791
Less FY03 "Carryover" Commitments from prior Council meetings		-1,437
Less FY03 Program Requirements		-11,000
Total		$ 56,683
	20% HPP	80% Regular
For FY 2003	$ 11,337	$ 45,346
Per council meeting	$ 3,779	$ 15,115

National Institute on Deafness and Other Communication Disorders
Budget Mechanism

(Dollars in thousands)

	FY 2003 Amended President's Budget	Percent of Total
Research Projects Grants	$262,754	71.8%
Research Centers	21,500	5.9%
Other Research	9,328	2.5%
Total, Res. Grants	293,582	80.2%
Individual Training	5,298	
Institutional Training	7,720	
Total, Training	13,018	3.6%
R&D Contracts	14,019	3.8%
Intramural Research	30,725	8.4%
Research Mgmt. & Support	14,585	4.0%
TOTAL	$365,929	

Appendix 5

NIDCD Advisory Council Operating Procedures

(As endorsed by Council January 31, 2003)

The Institute staff may take the following actions without Council review. All actions shall be documented and presented to the Council for its information at the first appropriate opportunity.

1. **Approval of New Principal Investigator or Program Director**
   Give approval of a new principal investigator or program director to continue an active grant at the grantee institution.

2. **Replacement of Research Grant for Investigator Who Moves to a New Institution**
   Make research grant awards equal to the remaining committed support for continuing work under the same principal investigator when that principal investigator moves from one institution to another. This provision will not be automatic, however. Staff may approve less than the remaining committed support and will in all cases carefully document for the file the rationale for the action.

3. **Awards for Orderly Termination**
   Make appropriate awards for orderly termination of competing continuation applications which were not recommended for further consideration, or which received a score too low for payment; this procedure is to be used in those cases where sudden termination of the grant would cause a serious loss of scientific material or impose a hardship to already employed personnel. In such cases, (1) the grant usually should be for a period not to exceed twelve months, (2) careful review should be given to needs for salaries and consumable supplies, (3) usually no funds would be provided for additional equipment or travel, and (4) in the case of training grants, support would be provided for those trainees already in the program.

4. **Awards for Interim Period Due to a Deferral**
   Make awards in an appropriate amount and for an appropriate interim period of time when a recommendation of deferral on a competing continuation application results in a loss of continuity of the active research or training program. Careful review should be given to the needs for personnel and consumable supplies; however, usually no funds would be provided for equipment or travel.

5. **Supplemental Support to Existing Research and Training Awards**
   Provide additional support up to $100,000 in direct costs per year to carry out the scientific, administrative and fiscal intent of the research or training award. The additional support may be necessary to: a) make NIH-wide supplemental awards for under-represented minorities, individuals reentering science, or individuals with disabilities; b) provide administrative increases; c) cover unanticipated costs; or d) ensure effective operation of the recommended program. Increases greater than $100,000 will be presented to the NDCD Advisory Council for approval before an award is made.

Institute staff may take the following actions without subsequent reporting to the Council.

1. **Continuation of Grant in Temporary Absence of Principal Investigator or Program Director.**
   Give approval for continuation of grants in the temporary absence of the principal investigator or program director.

2. **Extension of Project Period Dates**
   Take necessary action on extensions of project period end dates without additional funds.

3. **Scientific Evaluation Grants**
   Take final action in awarding supplements to the chairpersons of the NIDCD research and training review committees in an amount necessary to carry out the functions of the committees.